

REMARKS

This is in response to the Office Action mailed September 17, 2008, in which pending claims 249-253 and 273-285 were rejected. With this amendment, Applicant has amended claims 273, 276 and 277 and canceled claim 275. Reconsideration of the application as amended is respectfully requested.

Claim Rejections-35 U.S.C §103(a)

In the Office Action, the Examiner rejected claims 249-253 under 35 U.S.C §103(a) as being unpatentable over Suda et al. (US patent No. 5,978,712) in view of Barreras (US patent No. 5,807,397) and Spinelli et al. (US patent No. 7,328,068). Applicant believes that the rejections should be withdrawn for the reasons set forth below.

The present application is a continuation of pat 6,652,449, filed July 20, 2001, which was filed as a 371 application of international application No. PCT/IL99/00528, filed on October 5, 1999, which is a continuation of U.S. application No. 09/167,244, filed October 6, 1998. Exemplary support for claim 249 can be found in at least the Abstract; col. 4, lines 58-63; and col. 16, lines 49-59 of U.S. Pat. No. 6,652,449. However, the earliest possible claim of priority for Spinelli et al. is March 31, 2003, which is the filing date of U.S. Provisional Application No. 60/459,077. Therefore, Spinelli et al. is disqualified as prior art to the present application under 35 U.S.C §103(a).

Therefore, claim 249 is non-obvious in view of the cited references. Applicant requests that the rejection of claim 249 be withdrawn.

Additionally, claims 250-253 are believed to be in condition for allowance, at least for the reasons set forth above with regard to independent claim 249, from which they depend. Accordingly, Applicant requests that the rejections be withdrawn.

Claim Rejections-35 U.S.C §112

In the Office Action, the Examiner rejected claims 273-283 under 35 U.S.C. §112, first paragraph because the specification, while being enabling for implanting at least one electrode in

contact with a pelvic muscle, does not reasonably provide enablement for the electrode being in general alignment with a urethra. Applicant has amended claim 273 to eliminate “in general alignment with a urethra of a patient”. Accordingly, Applicant requests that the rejection be withdrawn.

Claim Amendments

Applicant has amended claim 273 to eliminate “in general alignment with a urethra of a patient” and added “providing for the electrical waveform a plurality of pulses each having pulse width duration of 2 ms or less”. The added subject matter was generally previously presented in claim 276, which has been canceled.

Amended claim 273 is similar to previously presented claim 244 (canceled), which was rejected in the Office Action mailed April 17, 2008 under 35 U.S.C. §103(a) as being unpatentable over Suda et al. (U.S. Patent No. 5,978,712) in view of Barreras (U.S. Patent No. 5,807,397). In rejecting the claim, the Examiner found Suda et al. to teach “that many parameters including pulse width are ‘arbitrarily set by the doctor or health worker in accordance with the state of urinary incontinence.’” (citing page 4, lines 17-28 of Suda et al.). Based on this finding, the Examiner concluded that:

a modification of the device [to] set the parameters to any needed level would have been obvious to one skilled in the art depending on the individual and particular state of incontinence. Clearly Suda et al. teaches that it would have been obvious to allow the device to be set to different parameters and the device is also used to treat urinary incontinence using electrodes implanted in the pelvic muscle, therefore to find the optimum workable ranges by routine experimentation would have been obvious to one skilled in the art as discussed above.

In making the rejection, the Examiner appeared to be relying on KSR International Co. v. Teleflex Inc., in which the Supreme Court stated that a person of ordinary skill in the art (POSA) has good reason to pursue the known options within his or her technical grasp “[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions” 127 S. Ct. 1727, 1742 (2007). However, the Federal Circuit (Ortho-McNeil Pharma. v. Mylan Labs, Fed. Cir., March 31, 2008, slip op. at 9-10) has recently

interpreted "a finite number of identified, predictable solutions" to mean "a finite, and in the context of the art, small or easily traversed, number of options", where subject matter outside that small, easily traversed number of options does not "support an inference of obviousness".

There are many different unpredictable variables that the POSA would face in determining the particular electrical waveform to apply to the pelvic muscle of a patient for the purpose of treating a condition of the patient. Exemplary variables for the electrical waveform include the current, the voltage, the pulse width, the frequency of the pulses, etc. (paragraphs [0172]-[0179] of the present application – U.S. Pub. No. 20050261746). With regard to the pulse width of an electrical waveform that is applied to a pelvic muscle of a patient, the options available to the POSA are nearly limitless. Therefore, the subject matter of claim 273 is far from “small or easily traversed”. As a result, a POSA would not be motivated to explore the copious options for the stimulation signal to ultimately lead to the electrical waveform described in claim 273 of the present application, as well the electrical waveforms described in claims 274 and 276-285.

Accordingly, claims 273, 274 and 276-285 are believed to be non-obvious in view of the cited references.

Conclusion

In view of the above remarks, Applicant believes that the present application is in condition for allowance. Reconsideration of the application as amended is respectfully requested.

The Director is authorized to charge any fee deficiency required by this paper or credit any overpayment to Deposit Account No. 23-1123.

Respectfully submitted,

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